

# UNITED STATES DEPARTMENT OF COMMERCE **United States Patent and Trademark Office**

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APPLICATION NO.	FILING DATE		FIRST NAMED IN	VENTOR		ATTORNEY DOCKET NO.	
09/326,285	06/07/99	SHEN			J	BB-1137	
Г						EXAMINER	]
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LEGAL PATEN WILMINGTON	JTS				1655	10	2-
					DATE MAILED	): 05/08/01	

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

1

		Application No.	Applicant(s)				
· Office Action Summary		09/326,285	SHEN, JENNIE BIH-JIEN				
			Art Unit				
	•	Examiner					
		Juliet C. Einsmann	1655				
 Period fo	The MAILING DATE of this communication appe	ears on the cover sneet w	ntn the correspondence address				
A SHO THE N - Extension after S - If the   - If NO - Faillur - Any re	DRTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. sions of time may be available under the provisions of 37 CFR 1.13 EXX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period to to reply within the set or extended period for reply will, by statute the ply received by the Office later than three months after the mailing of patent term adjustment. See 37 CFR 1.704(b).	36 (a). In no event, however, may within the statutory minimum of will apply and will expire SIX (6) M, cause the application to become date of this communication, ever	a reply be timely filed  hirty (30) days will be considered timely.  ONTHS from the mailing date of this communication.  ABANDONED (35 U.S.C. § 133).  if timely filed, may reduce any				
1)⊠	Responsive to communication(s) filed on 28 I		nd 30 Mar 2001				
2a) <u></u> □	71110 2001011 12 13 13 13 13 13 13 13 13 13 13 13 13 13	is action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Dispositi	on of Claims						
4) Claim(s) 1-150,169,170 and 172-176 is/are pending in the application.							
	4a) Of the above claim(s) <u>1-150, 169, 179</u> is/al	re withdrawn from consi	deration.				
5)							
6)⊠							
7)							
8) Claims are subject to restriction and/or election requirement.							
Applicati	ion Papers						
	The specification is objected to by the Examir	ier.					
10)	The drawing(s) filed on is/are objected	to by the Examiner.					
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved.							
12) The oath or declaration is objected to by the Examiner.							
_	under 35 U.S.C. <b>\$</b> 119						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. <b>\$</b> 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
	1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documents have been received in Application No						
*	3.☐ Copies of the certified copies of the pri application from the International B See the attached detailed Office action for a lis	ureau (PCT Rule 17.2(a	1)).				
14)⊠ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).							
1							
Attachme	nt(s)						
15) 🔀 No	ntice of References Cited (PTO-892) ortice of Draftsperson's Patent Drawing Review (PTO-948) ormation Disclosure Statement(s) (PTO-1449) Paper No(s	19) 🔲 Not	rview Summary (PTO-413) Paper No(s). <u>10</u> . ce of Informal Patent Application (PTO-152) er:				

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#### **DETAILED ACTION**

#### Election/Restrictions

- 1. Applicant's response to restriction requirement has been received (paper number 9).

  Applicant's election of group IX, methods for improving animal carcass quality, claims 151-168 and 171. These claims were subsequently cancelled and claims 172-176 were submitted therefore. Claims 172-176 will be examined herein.
- Applicant's arguments with regard to the restriction requirement have been considered. The examiner has agreed, for the group elected, to consider methods for improving carcass quality which in which the transgenic plants comprise either the complement or the reverse complement of the elected nucleic acid, or both. Further, the examiner will examine the claims in so far as they require any of the designated promoter fragments, that is all of SEQ ID NO: 19 or 38-49, since SEQ ID NO: 38-49 are merely subfragments of SEQ ID NO: 19.
- 3. In the interview (paper number 10) a further restriction was required between methods which utilize transgenic plants requiring SEQ ID NO: 9 and 11. Applicant elected SEQ ID NO: 9 for prosecution.

### Specification

- 4. The abstract of the disclosure is objected to because it does not adequately describe the elected invention. Correction is required. See MPEP § 608.01(b).
- 5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See, for example, page 14, line 36.

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6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

# Information Disclosure Statement

7. The information disclosure statements filed 10/14/99, 12/17/99, and 5/19/00 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but only the references present in the application file have been considered. The references lined through with no examiner's initials next to them were not present in the file at the time of examination.

# Claim Rejections - 35 USC § 112

### Second Paragraph

- 8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 9. Claims 172-176 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 172-176 are indefinite over the recitation of "carcass quality" because it is not clear from the specification to what characteristics of an animal this phrase refers, nor is it clear how one would judge such a characteristic.

Claims 172-176 are indefinite over the recitation of the phrase "carcass quality improving amount" because it is not clear exactly what amount of an animal feed would constitute a carcass

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quality improving amount. The specification provides no guidance in the determination of such an amount, and therefore the metes and bounds of this claim are unclear.

Claims 172-176 are indefinite because the active process steps are unclear. That is, it is not clear if the "feeding the animal" language is intended to be an active process step or part of the preamble of the claim. Clarification is required.

Claims 172-176 are indefinite over the recitation of "reverse complement" because it is not clear what this terminology means. For example, given the sequence 5'-CAT-3', the complement is 3'-GTA-5' or 5'-ATG-3'. It the reverse complement then 5'-GTA-3'?

Claims 172-176 are indefinite over the recitation of "a shrunken 1 intron/exon" because the meaning of this term is unclear. The specification at page 16 teaches that this phrase refers to "a region of the shrunken 1 gene from corn" but the specification does not state which region.

One example is given, however, in light of the broad definition in the specification, it is not clear what region the claim intends to be referring to.

Claims 172-176 are indefinite over the recitation of "or a functionally equivalent subfragment thereof." It is not clear, for example, if this phrase is referring to the nucleic acid in the chimeric gene or to SEQ ID NO: 9.

Claims 172-174, sections (ii) and (iv), and claim 175 (b) are indefinite over the phrase "the isolated nucleic acid fragment comprising a full length or partial corn" because this phrase is unclear. That is, it is not clear which nucleic acid is being referred to when the claim recites "the isolated…"

Claims 172-174, sections (ii) and (iv), claim 175 (b), and claim 176 are indefinite over the language "corn oleosin promoter hybridizes to the" because this language is unclear.

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Claims 172 and 173, section (ii), (iii) and (iv), claim 175, and claim 176 are indefinite because it is not clear what "operably linked to suitable regulatory sequences" modifies. That is, it is not clear from the language of the claim what is required to be operably linked to suitable regulatory sequences.

Claim 175 is indefinite over the recitation of "the corn grain" because this phrase lacks proper antecedent basis in the claims. The claim is further indefinite over the recitation of "not less than about" because it is not clear if 60% is meant to be a lower limit or something less than 60% is the lower limit.

### First Paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 172-176 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

\* Claims 172-176 are drawn to methods of improving animal carcass quality by feeding an animal a "carcass quality improving" amount of animal feed derived from transgenic plants which comprise chimeric genes as listed in the claims. These claims are broadly drawn in that they encompass methods for improving the carcass quality of any animal, and they do not specifically indicate the amount of feed necessary to effect the goal of improving carcass quality. Further, as discussed above, neither the claims nor the specification offer guidance as to how to

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measure carcass quality or what aspect of carcass quality would be improved by the consumption of the animal feed derived from the plants described in the claims.

The prior art provides no guidance as to the expected effects of feeding plants with altered lipid content on carcass quality of animals. Furthermore, experiments in the prior art indicate that the effects changes in feeding regimes will have on animal carcass quality are highly unpredictable. For example, Machev *et al.* (Zhivotnov"dni Nauki, (1996) Vol. 33, No. 3, p. 23-26) found that completely replacing maize with barley in animal feed had no significant effect on the slaughter and commercial value of pigs (ABSTRACT, p. 26). Certainly the difference in the nutritional content of barley versus maize in animal feed would be expected to be larger than the overall difference between wild type corn and the corn used in the present invention. Cooke *et al.* (Anim. Prod. (1971) Volume date 1970, 14(P1. 2) 219-28, ABSTRACT only) failed to demonstrate any significant interaction between dietary energy and protein in terms of carcass tissue proportions. These references are cited merely to demonstrate that it is highly unpredictable as to how feeding regimes will effect the carcass quality of animals.

The specification teaches plants with two different alterations in fatty acid content, some with increased saturated acid content, and some with oleic acid content. The specification provides no guidance as to how either type of plant can be used to improve carcass quality. The specification provides no guidance as to which animals will be expected to have their carcasses improved, during what part of the feeding regime the animals should be fed the plants comprising the chimeric genes, how much feed would be "a carcass quality improving amount" or how the ordinary practitioner should measure the improvement in carcass quality. The

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determination of such factors would require extensive experimentation with a wide variety of animals, and such experimentation would in itself be inventive.

Due to the broad nature of the claims, the lack of guidance in the specification or in the prior art, the high level of unpredictability with regard to the effects of feeding regimes on animal carcass quality, the lack of working examples, and the high level of experimentation necessary to determine the methodology necessary to practice the claimed invention, it is concluded that undue experimentation would be required to practice the claimed invention.

Furthermore, with regard to the plants that are described to be used as animal feed, the does not reasonably provide enablement for the claimed plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the plants commensurate in scope with these claims.

The specification teaches corn plants which have high stearic acid content (compared to wild type) in corn grains after transformation with chimeric constructs that contain either the anti-sense (pBN262) or sense (pBN264 or pBN427) strands of a truncated corn delta-9 desaturase (a truncated version of the full length SEQ ID NO: 9). The specification also teaches corn plants with high oleic acid content (compared to wild type) in corn grains after transformation with chimeric constructs that comprise a near full length fad2-1 coding region with the ATG out of frame (pBN257 (SEQ ID NO: 58) or construct pBN428). The specification discusses possible mechanisms for producing plants with high stearic acid content and high oleic acid content, but does not exemplify such plants.

The specification does not teach any general mechanism by which the introduced nucleic acids are effecting the fatty acid content of the plants. The specification does not teach a plants

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with a broad range in changes in fatty acid composition, only plants with high stearic acid content or high oleic acid content. The specification also does not teach plants which comprise both of the desaturases in which altered lipid content is observed.

It is highly unpredictable which nucleic acid sequences would result in the alteration of the lipid profile of plants. That is, although transformation of the plants with the corn deasturases described in the claims may be possible, the effect of using, for example, a full length sense copy of corn delta-9 stearoyl ACP desaturase on a plant is highly unpredictable. The specification teaches plants in which sense and anti-sense nucleic acids encoding corn delta-9 stearoyl ACP desaturase are introduced into plants, and in both instances the resulting plant displayed high saturate fatty acid composition. The mechanism by which this occurs is unclear, and therefore, it is not possible to predict the effect that adding other nucleic acids to the plants would have on the plant. Inhibition of the functioning of the native enzyme by an introduced nucleic acid is expected to be sequence dependent, and the specification provides no guidance as to how the instant nucleic acids can be altered so as to produce plants with similar alterations in fatty acid composition. The claims are broadly drawn to include the use of plants transformed with any portion of nucleic acids encoding a desaturase with 80% identity to the disclosed desaturase or with any functional fragment thereof. However, the specification provides no guidance as to how the nucleic acids of the examples can be modified and still have the same effect on a plant upon transformation of the plant with the nucleic acid. The experimentation necessary to determine other plants would require the production of many plants using many different nucleic acids, both sequence variants of the disclosed nucleic acids and fragments of the

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disclosed nucleic acids, assaying the produced plants for lipid content and analyzing the results for an association between different nucleic acids an changes in lipid content.

Due to the lack of guidance in the specification, the high level of experimentation that would be required to make other plants with altered lipid content, and the high level of unpredictability with regard to which nucleic acids would be useful for producing such plants, undue experimentation would be required to produce animal feed from plants as broadly claimed.

12. Claims 172-176 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to a method which improving animal carcass quality which comprise feeding the animal feed derived from transgenic plants comprising chimeric molecules which comprise nucleic acids encoding a corn delta-9 stearoyl ACP desaturase which has an amino acid sequence with 80% identity to SEQ ID NO: 9, nucleic acids encoding a corn delta-12 desaturase wherein the nucleic acid has 80% sequence identity to SEQ ID NO: 1, or functional fragments of either of these two nucleic acids. Further, the claims include plants comprising promoters with 80% identity to SEQ ID NO: 19 or 38-49 or which hybridize to SEQ ID NO: 19 and 38-49 under moderate stringency conditions. This large genus is represented in the specification by only SEQ ID NO: 9, SEQ ID NO: 1, or SEQ ID NO: 19 and 38-49, as appropriate. Further, the response of the plants produced largely depends on the functionality of

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the sequence introduced. Thus, applicant has express possession of only single species in a genus which comprises hundreds of millions of different possibilities.

With regard to the written description, all of these claims encompass nucleic acid sequences different from those disclosed in the specific SEQ ID No:s which, for claims 172-176 include modifications by permitted by the % identity language or the "functionally equivalent subfragment" language for which no written description is provided in the specification.

Especially with regard to the functionally equivalent subfragment language, the mechanism by which the introduced nucleic acids act in plants is unknown, and therefore the "function" of the nucleic acids in the plants is unknown.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the SEQ ID NO: 1 is described. Also, in <u>Vas-Cath Inc. v.</u> Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception or written description of any plants containing chimeric genes modified by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID Nos but retaining correlative function in the claimed product.

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#### Conclusion

13. No claims are allowed.

14. Nucleic acids consisting of SEQ ID NO: 19 and 38-49 are free of the prior art.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

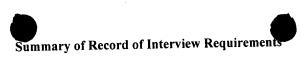
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

JEFFREY FREDMAN PRIMARY EXAMINER Juliet C. Einsmann Examiner Art Unit 1655

May 4, 2001

C	Application No.	Applicant(s)
	09/326,285	SHEN, JENNIE BIH-JIEN
Interview Summary	Examiner	Art Unit
	Juliet C. Einsmann	1655
All participants (applicant, applicant's representative, PTC	) personnel):	
(1) Juliet C. Einsmann.	(3)	
(2) Lynne Christenbury.	(4)	
Date of Interview: 29 March 2001.		
Type: a)⊠ Telephonic b)□ Video Conference c)□ Personal [copy given to: 1)□ applicant	2) applicant's representat	tive]
Exhibit shown or demonstration conducted: d)☐ Yes If Yes, brief description:	e) No.	
Claim(s) discussed: <u>172-176</u> .		
Identification of prior art discussed: none.		
Agreement with respect to the claims f)☐ was reached	d. g)□ was not reached. h	n)⊠ N/A.
Substance of Interview including description of the gener reached, or any other comments: <u>See Continuation She</u>	<u>eet</u> .	
(A fuller description, if necessary, and a copy of the ame allowable, if available, must be attached. Also, where no allowable is available, a summary thereof must be attach	copy of the amendments that	agreed would render the claims It would render the claims
i) It is not necessary for applicant to provide a checked).		
Unless the paragraph above has been checked, THE FO MUST INCLUDE THE SUBSTANCE OF THE INTERVIE action has already been filed, APPLICANT IS GIVEN OF STATEMENT OF THE SUBSTANCE OF THE INTERVIT reverse side or on attached sheet.	EW. (See MPEP Section 713. NF MONTH FROM THIS INTE	ERVIEW DATE TO FILE A
Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.	Examiner's	signature, if required



Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

## Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
  - (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### **Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

#### Continuation Sheet (PTO-413)

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant was informed of the following: (1) Methods utilizing all of the promoter sequences would be examined because SEQ ID NO: 38-49 are merely sub-fragments of SEQ ID NO: 19. (2) Claims which require both the corn delta 9 and the corn delta 12 desaturases are considered a combination of the claims which require only one. Both the combination and subcombination claims will be examined. Applicant was therefore required to select either SEQ ID NO: 9 or SEQ ID NO: 11 to be examined for the corn delta 9 desaturase. Applicant elected SEQ ID NO: 9 for examination. (3) Applicant was informed that consideration of the claims would also consider nucleic acids which comprise the reverse complement of the elected sequences (SEQ ID NO: 1 and SEQ ID NO: 9).

Applicant was also requested to submit new copies of the non-patent literature cited on the previously submitted 1449's since these had been separated from the file. Applicant agreed to send the papers.